

## **REMARKS**

### **Amendments to the claims**

Claims 59-90 are pending in the application. Claims 59, 61, 63, 71, 73, 78, 79, 81, 82, 84, 86-88 and 90 have been amended. Claims 60, 62, 64-67, 70, 72, and 74-77 have been canceled without prejudice. Applicant reserves the right to file the canceled claims in a divisional or continuation application. New claims 91 and 92 have been added.

Support for the amendments to claim 79 can be found, for example, at the end of page 38, at the beginning of page 39, and in example 1, pages 41 and 42 of the specification. Support for claims 86-88 as amended can be found, for example, at pages 20-24 of the specification.

Support for new claim 91 can be found, for example, in example 2, pages 43 and 44 of the specification. New claim 92 has been obtained from claim 86 and is directed to a method for production of human lactoferrin extracts.

No new matter has been added.

### **Claim objections**

In the Action, the Examiner objects to claim 59 because directed in part to a nonelected invention. The Applicant has amended claim 59 and believes that the objection of the Examiner has been overcome.

### **Claim rejections – 35 USC § 112, first paragraph**

In the Action, the Examiner rejects claims 59-63, 68-73 and 78-85 under 35 USC § 112, first paragraph as failing to comply with the written description requirement.

The Applicant has amended claim 59 to recite “*DNA sequences coding for the promoter and the leader sequence of the soybean protein 7S basic globulin.*” However, the Applicant has not limited claim 59 to SEQ. ID. Nos. 1, 13, and 21 as also requested by the Examiner. The Applicant respectfully traverses such requirement for the reasons that follow.

The present application discloses the amino acid sequence of the human lactoferrin (see SEQ. ID. NO. 1) and a synthetic DNA sequence with codons selected for expression in plant coding the same.

According to MPEP § 2163.II.A.3(a)ii. (8<sup>th</sup> ed. rev. 2. 2001), *"in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence"* (emphasis added).

Reference is also made to the CAFC decision *In Re David Wallach* (03-1327, Serial No. 08/485,129, August 11 2004), enclosed with the present response. The Court states, at page 6, that there is *"no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is, as explained above, a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it"* (emphasis added).

In view of the above, the Applicant respectfully submits that the DNA sequence coding human lactoferrin of the expression cassette should not be limited to those specifically disclosed in the application. In accordance with the MPEP and the CAFC decision above, the disclosure of the amino acid sequence of human lactoferrin (see SEQ. ID NO. 1) provides sufficient support for nucleic acid sequences encoding such amino acid sequence. Therefore, the Applicant submits that the above rejected claims satisfy to the requirements of 35 USC 112, first paragraph.

#### **Claim rejections – 35 USC § 112, second paragraph**

In the Action, the Examiner rejects claim 59 (and claims 60-73 and 78-82 dependent thereon) under 35 USC § 112, second paragraph because of the language "allowing in-seed tissue specific expression of non-degraded human lactoferrin." The Applicant has amended claim 59 as shown in the enclosed listing of claims and submits that the rejections of the Examiner has been overcome.

Further, the Examiner rejects claim 59 (and claims 60-73 and 78-85 dependent thereon) under 35 USC § 112, second paragraph because of the language "a regulation element of

protein basic globulin 7S." The Applicant has amended claim 59 to recite "*DNA sequences coding for the promoter and the leader sequence of the soybean protein 7S basic globulin*" and believes that also this rejection has been overcome.

Still further, the Examiner rejects claims 60 (and claim 61 dependent thereon), 62 (and claim 63 dependent thereon), 70 (and claim 71 dependent thereon), 72 (and claim 73 dependent thereon), and 78 as indefinite in the recitation of the term "includes." The Applicant has canceled claims 60, 62, 70 and 72, thus rendering the rejection of the Examiner moot as to those claims. Additionally, claim 78 has been amended and is submitted to overcome the rejection of the Examiner.

Still further, the Examiner rejects claim 79 because no method steps are disclosed. The Applicant has amended claim 79 and believes that the rejection of claim 79 has been overcome.

Still further, the Examiner rejects claims 80-82 because of the recitation "obtainable from." The Applicant respectfully submits that such recitation is not present in claim 80. Further, claim 81 has been amended to recite "obtained", thus overcoming the objection of the Examiner as to claims 81 and 82.

Still further, the Examiner rejects claim 82 because of the recitation "said aggregations: and "capable of regenerating transgenic plants." The Applicant has amended claim 82 as shown in the enclosed listing of claims, and submits that the rejection has been overcome.

Still further, the Examiner rejects claim 84 because of the recitation "fruit bearing plants" and "horticultural plants." The Applicant has amended claim 84 as shown in the enclosed listing of claims, and submits that the rejection has been overcome.

#### **Claim rejections – 35 USC § 101**

In the Action, the Examiner rejects claim 79 under 35 USC § 101 because no method steps are disclosed. The Applicant has amended claim 79 as shown in the enclosed listing of claims, and submits that the rejection has been overcome.

**Claim rejections – 35 USC § 102**

In the Action, the Examiner rejects claims 59-60, 62, 68 and 69 as being anticipated by Watanabe. Further, the Examiner rejects claims 59, 68, 69 and 79-85 as being anticipated by Salmon. The Applicant respectfully disagrees.

With reference to claims 60 and 62, those claims have been cancelled, thus rendering the rejection of the Examiner moot.

Claim 59 as amended now recites an *"expression cassette"* which *"expresses in-seed, with tissue specific expression, a non-degraded human lactoferrin."* The Examiner has expressly stated that such feature is not disclosed in Watanabe or Salmon. Further, claim 59 as amended also recites that the cassette comprises *"a gene encoding human lactoferrin . . . linked to DNA sequences coding for the promoter and the leader sequence of soybean protein 7S basic globulin."*

Therefore, the Applicant submits that claim 59 is novel over Watanabe and Salmon, together with 68, 69 and 79-85, by virtue of their dependency on claim 59.

**New claims**

New claims 91 and 92 have been added. Those claims are submitted to be patentable over the cited art.

\* \* \*

The Applicant submits that all claims of the application as amended herein are in condition for allowance. Prompt issuance of a Notice of Allowance is earnestly solicited.

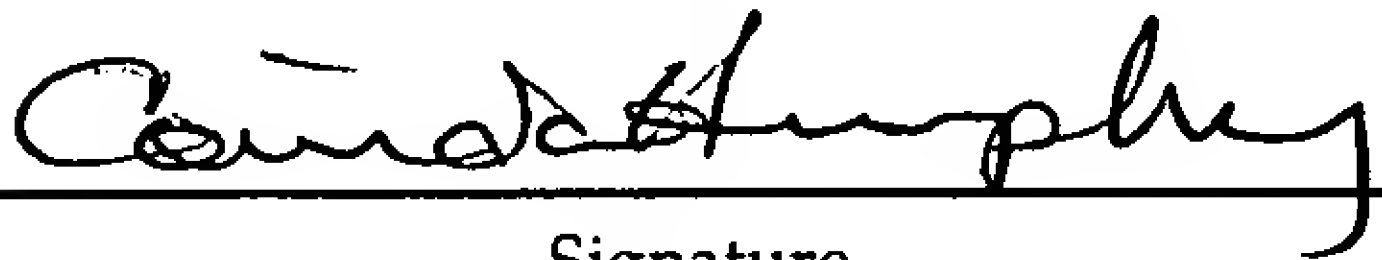
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Examiner: Collins, Cynthia E  
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The Commissioner is authorized to charge any additional fees which may be required or credit overpayment to deposit account no. 12-0415. In particular, if this response is not timely filed, then the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136 (a) requesting an extension of time of the number of months necessary to make this response timely filed and the petition fee due in connection therewith may be charged to deposit account no. 12-0415.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 on

April 19, 2005  
(Date of Deposit)

Corinda Humphrey  
(Name of Person Depositing)



Signature

April 19, 2005

Date

Respectfully submitted,



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Enclosures:

- Petition for one-month extension
- One-month extension fee in the sum of \$ 60.00
- CAFC decision 03-1327 of August 11, 2004
- Postcard